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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,142	01/09/2001	Wilhelm Amberg	BBI-6026CPCN	6617

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EXAMINER
CELSA, BENNETT M

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary

Application No.	Applicant(s)
09/757,142	Amberg et al.
Examiner	**Art Unit**
Bennett Celsa	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above, claim(s) *8 and 9* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7 and 10* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-10 are currently pending.

Claims 1-7 and 10 are under consideration.

Claims 8-9 are withdrawn from consideration as being directed to a nonelected invention.

NOTE: the location of the present application is ART UNIT 1639.

Election/Restriction

1. Claims 8-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention of Groups II and III. Election, with traverse, was made traverse in Paper No. 14 of Group 1 claims 1-7 with the election of the compound of Example 2 .

2. The traversal is on the ground(s) that:

A. Group I, II, and III represent "different embodiments of a single inventive concept for which a single patent should issue" and "Moreover, the patent statutes require that an applicant disclose ... how to make and use the claimed invention"; and

B. Applicant argues that there is not "serious burden" to search the compounds along with its method of use and making since there is "substantial overlap" and "given the data bases and power search engines at the Examiner's disposal ...".

This is not found persuasive because the restriction provides reasons for patentable distinctness between the Group I, II and III inventions (e.g. see office action pages 2 and 3) and additionally provides rationale as to why it would constitute a serious burden to examine in one application the

distinct inventions of Groups I, II and III including different classifications and the use of different manual and computer bibliographic/classification/ searches .

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

3. Claims 1-7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 1-7 (and claims dependent thereon) use of the term "Novel" should be deleted.

B. In claims 1, 3 and 4 the phrase "**in which residues one CH2 group** may be replaced" lacks proper grammar as to permit a clear interpretation of the intended scope.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haupt et al., U.S. Pat. No. 5,831,002 (11/98: filed 6/7/95 or earlier).

Haupt et al. disclose a generic which encompasses species which overlap with the presently claimed invention and thus render the overlapping peptides obvious to one of ordinary skill in the art which would be motivated to make such overlapping peptides to achieve antineoplastic compounds. For example, the patent claim 1 wherein R1 is alkyl; R2 is hydrogen; or R1- N- R2 come together to form a 5-6 member nitrogen containing ring; X is alkyl; A,B,D,E are as presently claimed; s is 1; t is 0; u is 0 or 1; and K corresponds to an amine moiety R5-N-R6 wherein R5 and R6 are independently hydrogen or unsubstituted or substituted alkyl including ethers or R5 and R6 form a ringed structure for example a four ringed heterocycle containing N in the ring; or a six membered ring containing N and O. Additionally, for further selections of K values columns 55-57 could be selected including Xkv, Xky, Xld, Xlf, Xll, Xlm, Xls, Xlt, Xlu, Xma.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-7 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,103,698.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims a composition that comprises a generic compound which encompasses species which overlap with the presently claimed invention and thus render the overlapping peptides obvious to one of ordinary skill in the art . For example, the patent claim 1 wherein all of the claim 1 variables are present as described and S=1 ; and either U=1 and T=0 or U=0 and T=1.

7. Claims 1-7 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,015,790.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims methods which utilize a composition that comprises a generic compound which encompasses species which overlap with the presently claimed invention and thus render the overlapping peptides obvious to one of ordinary skill in the art . For example, the patent claim 1 wherein all of the claim 1 variables are present as described and S=1 ; and either U=1 and T=0 or U=0 and T=1.

8. Claims 1-7 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,831,002 .

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims a generic which encompasses species which overlap with the presently claimed invention and thus render the overlapping peptides obvious to one of ordinary skill in the art. For example, the patent claim 1 wherein R1 is alkyl; R2 is hydrogen; or R1- N- R2 come together to form a 5-6 member nitrogen containing ring; X is alkyl; A,B,D,E are as presently claimed; s is 1; t is 0; u is 0 or 1; and K corresponds to an amine moiety R5-N-R6 wherein R5 and R6 are independently hydrogen or unsubstituted or substituted alkyl including ethers or R5 and R6 form a ringed structure for example a four ringed heterocycle containing N in the ring; or a six membered ring containing N and O. Additionally, for further selections of K

values columns 55-57 could be selected including Xkv, Xky, Xld, Xlf, Xll, Xlm, Xls, Xlt, Xlu, Xma (see also third and second to last substituent of K substituent in claim 4 which encompasses K values within the scope of the presently claimed invention.)

9. Claims 1-7 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,965,700.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims a method which encompasses species which are within the scope of the presently claimed invention and thus render the overlapping peptides obvious to one of ordinary skill in the art which would be motivated to make such overlapping peptides to achieve antineoplastic compounds.

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)
January 29, 2003

BENNETT CELSA
PRIMARY EXAMINER